IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

ALLEN LEFAIVRE, individually and on behalf of all others similarly situated, Plaintiff(s), v. KV PHARMACEUTICAL COMPANY, ETHEX CORPORATION, and THER-RX CORPORATION, Defendant(s).	§ § § § § § § § § § §	Case No.: 4:09-cv-00588 SNL

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO
DEFENDANTS' MOTION TO DISMISS FIRST AMENDED COMPLAINT

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TREATISES AND OTHER

Plaintiff, Allen Lefaivre, files Plaintiff's Memorandum in Opposition to Defendants' Motion to Dismiss Plaintiff's First Amended Complaint, responding to Defendants' Rule 12(b)(6) Motion to Dismiss Plaintiff's Amended Complaint [Doc. 25] and Memorandum of Defendants KV Pharmaceutical Company, ETHEX Corporation and Ther-Rx Corporation ("Defendants") in Support of Their Motion to Dismiss Plaintiff's First Amended Complaint [Doc. 26] ("Memorandum"), and for such would respectfully show the Court as follows:

I.

INTRODUCTION

In the Memorandum, Defendants request dismissal of Mr. Lefaivre's causes of action as pled in his First Amended Class Action Complaint [Doc. 21] ("Amended Complaint"). None of the grounds for dismissal asserted by Defendants have merit.

Initially, without even specifying the applicable type, Defendants claim that federal law preempts Mr. Lefaivre's state law causes of action. However, when the Court analyzes Mr. Lefaivre's claims under the latest Supreme Court pronouncements on preemption, it will find that neither express preemption nor field preemption nor conflict preemption bars Mr. Lefaivre's causes of action.

As to Mr. Lefaivre's cause of action for breach of the implied warranty of merchantability, Defendants claim that Rhode Island law governs and that Mr. Lefaivre has failed to plead privity and notice as required under Rhode Island law. Application of the Restatement's "most significant relationship" test as adopted by Missouri dictates the application of Missouri law to Mr. Lefaivre's claim because the most significant factor is the fact that Defendants' conduct causing injury to Mr. Lefaivre and the other members of the Class occurred

in Missouri. Under Missouri law, neither privity nor notice is required. However, if it is necessary, Mr. Lefaivre has pled notice in the Amended Complaint. Alternatively, even under Rhode Island law, privity is not required and Mr. Lefaivre gave notice to Defendants by filing and serving the Original Class Action Complaint and the Amended Complaint on them.

Finally, Defendants claim that Defendant Ther-Rx is not a proper Defendant and should be dismissed because Mr. Lefaivre has allegedly not pled that it participated in the manufacture or marketing of the Tablets. In fact, Mr. Lefaivre has pled that Defendants, including Ther-Rx, manufactured and distributed the Tablets, requiring rejection of Defendants' argument.

II.

CORRECTION OF FACTUAL MISREPRESENTATIONS

In the Memorandum, Defendants misrepresent certain factual allegations in the Amended Complaint, as well as the substance of portions of the exhibits Defendants attached to the Memorandum. While not directly relevant to the Court's analysis of Defendants' request for dismissal under Rule 12(b)(6), Mr. Lefaivre corrects these misrepresentations so that the Court does not develop an incorrect impression of either the factual background or the merits of this case.

At several instances in the Memorandum, Defendants claim that: (1) they issued a recall notice, (2) in which they offered Mr. Lefaivre a refund for the purchase price of the Tablets, (3) Mr. Lefaivre received it, and (4) he refused to accept the refund offer and thereby failed to mitigate his damages. Memorandum at 1, 6, 8, & 13. Parts two through four of that claim are false. Nowhere in the Amended Complaint does Mr. Lefaivre allege that he received a recall notice from Defendants; rather, he alleges that he received a written notice from his prescription drug plan that Defendants' Tablets had been recalled at the urging of FDA. Amended Complaint

¶ 14. Moreover, the recall notice that Defendants falsely claim Mr. Lefaivre received does not purport to offer any refund or credit to consumers such as Mr. Lefaivre, but rather only to retail pharmacies. Memorandum, Exh. 3. Crucially, Mr. Lefaivre makes no allegation and references no document in which Defendants (or any entity) offered him any refund or credit for any of the Tablets, much less an allegation that he refused to accept such a credit or refund. Factually, no basis exists for Defendants' claim that Mr. Lefaivre failed to mitigate his damages.

Defendants also state that "the recall notice itself advised consumers to continue taking their medication." Memorandum at 4 (*citing* Exh. 3 to Memorandum). Notwithstanding the fact that Mr. Lefaivre never received Defendants' recall notice, the recall notice that Defendants submit to the Court simply does not contain any such advice. *Compare* Memorandum at 4 *with* Memorandum, Exh. 3.

Finally, Defendants characterize the FDA enforcement action and Consent Decree as reflecting "only allegations made by the FDA," such that Defendants never actually admitted any problem with the Tablets. Memorandum at 5 (*citing* Exh. 1 & 2). Contrary to this assertion, the recall notice that Defendants issued states that "ETHEX Corporation is voluntarily recalling all lots of [the Tablets] because they may potentially have been manufactured under conditions that did not sufficiently comply with cGMP's." Memorandum Exh. 3 (p. 1 of 4). In light of Defendants' representations to wholesalers and retailers across the country in its recall notice that its Tablets were potentially not manufactured properly, Defendants' representation to the Court in its Memorandum that Defendants never admitted any problem with the Tablets is not fully accurate at best.

III.

FEDERAL LAW DOES NOT PREEMPT MR. LEFAIVRE'S CAUSES OF ACTION

Defendants argue that the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301, *et seq.* ("FDCA"), bars Mr. Lefaivre's two state law causes of action, but they curiously do not specify which of the three preemption doctrines recognized in federal jurisprudence purportedly applies to preempt Mr. Lefaivre's causes of action. Memorandum at 7-11. In fact, Defendants claim not to be making a federal preemption argument at all, but rather merely enforcing § 337(a)'s grant of exclusive jurisdiction to the FDA to enforce the Act. *Id*. at 10-11.

Defendants are incorrect. Federal preemption is "[t]he principle (derived from the Supremacy Clause) that a federal law can supersede or supplant any inconsistent state law or regulation." BLACK'S LAW DICTIONARY 1197 (7th ed. 1999). Because Defendants assert that the FDCA effectively supplants any state law causes of action for damages based on allegations that prescription drugs are adulterated, they clearly make a preemption argument. Indeed, several of the cases Defendants cite recognized that analysis under one or more of three specific preemption doctrines -- express preemption, field preemption, or conflict preemption – is required in order to determine whether a state law cause of action is superseded or supplanted by the FDCA. *See, e.g., Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001); *Riley v. Cordis Corp.*, 2009 WL 1606650 (D. Minn. 2009); *Animal Legal Defense Fund Boston, Inc. v. Provimi Veal Corp.*, 626 F. Supp. 278 (D. Miss. 1986). Accordingly, Defendants have the burden to demonstrate that the FDCA preempts Mr. Lefaivre's state law causes of action, either through express, field, or conflict preemption, pursuant to the latest Supreme Court pronouncements on preemption.

When the Court examines those Supreme Court cases and analyzes Defendants' argument under the three preemption doctrines, it will recognize that Defendants have not met their burden and that none of the doctrines preempts Mr. Lefaivre's causes of action. The FDA's determination that Defendants' Tablets purchased by Mr. Lefaivre and the members of the Class were adulterated as defined by the FDCA does not foreclose Mr. Lefaivre's causes of action for breach of warranty and for violations of the MPA, which are claims for damages that do not conflict with, but rather complement, the FDA's successful action for injunctive relief. The Court should reject Defendants' preemption argument accordingly.

A. PREEMPTION STANDARDS AND PRESUMPTIONS.

Under the Supremacy Clause, federal law may potentially invalidate or supersede contrary state law in three different ways. U.S. CONST. art. VI, cl. 2; *Hillsborough Co. v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 712-13 (1985). "Express preemption" refers to when Congress expressly states in a statute that it preempts state law. *Hillsborough Co.*, 471 U.S. at 713; *see also Jones v. Rath Packing Co.*, 430 U.S. 519 (1977). If Congress does not expressly preempt state law, two types of implied preemption may nevertheless apply. "Field preemption" refers to when "Congress' intent to preempt all state law in a particular area may be inferred where the scheme of federal regulation is sufficiently comprehensive to make reasonable the inference that Congress 'left no room' for supplementary state regulation." *Hillsborough*, 471 U.S. at 713 (*citing Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). "Conflict preemption" refers to when state law actually conflicts with federal law, such that compliance with both federal and state regulation is physically impossible or state law stands as an obstacle to the purposes and objectives of Congress. *Hillsborough*, 471 U.S. at 713 (*citing Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963)).

Importantly, regardless of the type, a strong presumption against preemption exists, as a court must "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Wyeth v. Levine*, -- U.S. --, 129 S. Ct. 1187, 1194-95 (2009) (*quoting Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)). In every preemption case, "the purpose of Congress is the ultimate touchstone." *Wyeth*, 129 S. Ct. at 1194 (*quoting Lohr*, 518 U.S. at 485)). Crucially, "[t]he party contending that a claim is preempted bears the burden of establishing preemption." *Peters v. Astrazeneca, LP*, 417 F. Supp. 2d 1051, 1055 (W.D. Wis. 2006).

Accordingly, to carry their burden of demonstrating that the FDCA preempts Mr. Lefaivre's causes of action, Defendants must overcome the strong presumption against preemption by showing that Congress actually intended to foreclose Mr. Lefaivre's claims. Defendants, however, fail to make this showing, because not only do they fail to demonstrate the applicability of any of the three types of preemption, they fail to even specify the applicable doctrine, leaving the Court to guess at which of these preemption doctrines, if any, even potentially supports their argument. Memorandum at 7-11. Thus, the Court should summarily reject Defendants' preemption argument, as Defendants' nebulous assertions palpably fail to discharge Defendants' burden to overcome the strong presumption against preemption. Regardless, an analysis of Defendants' argument under each of the three preemption doctrines demonstrates dispositively that Mr. Lefaivre's causes of action are not preempted.

B. EXPRESS PREEMPTION DOES NOT BAR MR. LEFAIVRE'S CAUSES OF ACTION.

Defendants do not explicitly claim that the FDCA expressly preempts Mr. Lefaivre's causes of action. Memorandum at 5-9. However, at the beginning of their preemption argument, Defendants quote from 21 U.S.C. § 337(a), which provides that "all such proceedings for the

enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." Memorandum at 7. That language does not expressly preempt Mr. Lefaivre's causes of action.

More than thirty years ago, the Supreme Court examined the language of the FDCA and held that it does not contain any language expressly preempting state law claims involving prescription drugs. Specifically, in *Jones v. Rath Packing Co.*, the Supreme Court contrasted the language of the FDCA with the language of another federal statute, the Fair Packaging and Labeling Act, 15 U.S.C. § 1451, *et seq.* ("FPLA"), as follows: "**The FDCA contains no preemptive language**. The FPLA, on the other hand, declares that 'it is the express intent of Congress to supersede any and all laws of the States or political subdivisions thereof insofar as they may now or hereafter provide for the labeling of the net quantity of contents of the package of any consumer commodity covered by this chapter….'" *Jones*, 430 U.S. at 539 (*quoting* 15 U.S.C. § 1461) (emphasis added). Notably, the Supreme Court did not identify 12 U.S.C. § 337(a) as an express preemption provision, *id.*, presumably because Congress stating that proceedings to enforce or restrain violations of the FDCA shall be brought by the United States is a far cry from Congress declaring that it intends to supersede all state law dealing with prescription drugs.

Only five months ago, in *Wyeth v. Levine*, the Supreme Court reiterated the conclusion it reached more than thirty years earlier in *Jones*. In reviewing the origin and legislative history of the FDCA, the Supreme Court stated:

> If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's seventy-year history. But **despite its 1976 enactment of an express pre-emption provision for medical devices**, *see* § 521, 90 Stat. 574 (codified at 21 U.S.C. § 360k(a)), **Congress has not enacted such a provision**

> **for prescription drugs.** *See Riegel [v. Medtronic, Inc.,]* 552 U.S., at ---, 128 S. Ct. [999,] 1009 [2008] ("Congress could have applied the preemption clause to the entire FDCA. It did not do so but instead wrote a pre-emption clause that applies only to medical devices").

Wyeth, 129 S. Ct. at 1200 (citations and quotation in original) (emphasis added).

Because medical devices are not at issue in this case, Defendants can derive no support for an express preemption argument from 21 U.S.C. § 360k(a), the express preemption provision for medical devices contained in the FDCA. That leaves only the language of 21 U.S.C. § 337(a), and the Supreme Court's decisions in *Jones* and *Wyeth* make abundantly clear that 21 U.S.C. § 337(a) cannot support an express preemption argument in connection with claims involving prescription drugs. *Jones*, 430 U.S. at 539; *Wyeth*, 129 S. Ct. at 2000.

Defendants might try to distinguish these Supreme Court decisions from this case on the ground that the Supreme Court addressed whether the FDCA contained any language preempting state law damages claims based on violation of state law standards, not state law damages claims based upon a violation of the FDCA itself. That argument will not avail Defendants because § 337(a) only grants the FDA the exclusive right to enforce or restrain violations of the Act, and the enforcement mechanisms provided by the Act include actions for seizure of products, actions to recover injunctive relief, recommendations for the filing of criminal charges and, in some situations, the assessment of civil monetary penalties. *See* 21 U.S.C. §§ 332(a), 333(a), 333(b), 333(f), 334, 335(a) & 360(pp). They do not include the right to seek damages on behalf of injured consumers. Since an action for damages is not one of the provided methods for enforcement of the Act, § 337(a) does not give exclusive jurisdiction over such an action to the FDA, and, therefore, it cannot be viewed as expressly preempting a cause of action for damages, even one based on violation of the FDCA.

In summary, because the FDCA contains no expressly preemptive language applicable to Mr. Lefaivre's state law causes of action to recover damages, express preemption does not bar them.

C. FIELD PREEMPTION DOES NOT BAR MR. LEFAIVRE'S CAUSES OF ACTION.

Defendants do not explicitly assert that field preemption applies to bar Mr. Lefaivre's causes of action. Memorandum at 7-11. If the Court, however, decides to construe Defendants' argument as a request for the application of the doctrine of field preemption, the Court should reject that argument.

In *Wyeth*, the Supreme Court extensively discussed the origin and legislative history of the FDCA. *Wyeth*, 129 S. Ct. at 1195-96, 1199-1200. Throughout its discussion, the Supreme Court made abundantly clear that, in connection with prescription drugs, Congress was keenly aware of the operation and availability of state law remedies at the time it passed the statute, and that it affirmatively chose not to foreclose such remedies through its enactment of the FDCA and its various amendments. *See, e.g., Wyeth,* 129 S. Ct. at 1200 ("Its silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.").

In light of Defendants' failure to articulate a basis for the application of the field preemption doctrine, Memorandum at 7-11, and in light of the Supreme Court's analysis of the FDCA in *Wyeth* demonstrating the intent of Congress to continue the operation of state law in connection with prescription drug claims notwithstanding its enactment and amendment of the FDCA, 129 S. Ct. at 1200, the Court should flatly reject any argument that the doctrine of field preemption applies to bar Mr. Lefaivre's causes of action.

D. CONFLICT PREEMPTION DOES NOT APPLY TO BAR MR. LEFAIVRE'S CAUSES OF ACTION.

As with the doctrines of express preemption and field preemption, Defendants do not contend specifically that the doctrine of conflict preemption applies to bar Mr. Lefaivre's causes of action. Memorandum at 7-11. However, Defendants' preemption argument is perhaps most appropriately construed as a request that the Court apply the doctrine of conflict preemption, based on Defendants' allegations that Mr. Lefaivre, through his causes of action, is "attempt[ing] to leverage FDA allegations [sic] into a claim for economic damages," Memorandum at 8, and based on the cases Defendants cite which discuss the application of some unspecified type of preemption in connection with pharmaceutical companies suing each other under the Lanham Act, 15 U.S.C. §§ 1051, *et seq.*, and, in some cases, also under state law. *See generally* Memorandum at 9.

1. The Supreme Court's Rejection of Conflict Preemption in *Wyeth v. Levine* Demonstrates the Inapplicability of Conflict Preemption to Mr. Lefaivre's Causes of Action, and Defendants Admit That the Possible Bases for a Conflict are Absent in This Case.

Neither of the two types of conflict recognized by the Supreme Court exist in this case. First, it is not physically impossible for Defendants to both comply with the FDCA and the consent judgment entered into with the FDA and pay damages as a result of Mr. Lefaivre's state law causes of action. Second, requiring Defendants to pay damages for selling adulterated drugs does not obstruct the purposes and objectives of either the FDCA, which seeks to prevent the sale of such drugs, or the consent judgment, which puts measures in place to assure that Defendants sell no more adulterated drugs in the future. In fact, the assessment of damages against Defendants enhances the attainment of these goals.

Wyeth conclusively supports that neither type of conflict exists in this case. *Wyeth*, 129 S. Ct. at 1204. In *Wyeth*, the Supreme Court rejected the defendant's conflict preemption argument and affirmed a judgment in favor of the plaintiff based on her state law failure-to-warn claims against a manufacturer of an antihistamine whose warning label had been approved by the FDA. 129 S. Ct. at 1190-91. Initially, it rejected the defendant's assertion that conflict preemption barred the plaintiff's causes of action because it was ostensibly impossible for the defendants to comply with both federal and state requirements. 129 S. Ct. at 1199. Then, it rejected the defendant's contention that requiring it to comply with a state law duty to provide a stronger warning on the label than previously approved by the FDA would obstruct the purposes and objectives of federal drug labeling regulation. *Id.* at 1204.

In doing so, the Supreme Court specifically cited to the legislative history of the original version of the FDCA, in which witnesses testified before Congress that it was not necessary to include a federal cause of action for damages in the Act because common law claims were already available under state law. 129 S. Ct. at 1199 n. 7 (*citing* Hearings on S. 1944 before a Subcommittee of the Senate Committee on Commerce, 73d Cong., 2d Sess., 400, 403 (1933)). The Supreme Court also remarked: "In keeping with Congress' decision not to preempt common-law tort suits, it appears that the FDA traditionally regarded state law as a complementary form of drug regulation." 129 S. Ct. at 1202.

Wyeth thus makes clear that conflict preemption does not bar Mr. Lefaivre's claims. Mr. Lefaivre's causes of action for damages are precisely the sort of state law claims that Congress understood consumers would pursue. That Mr. Lefaivre uses the definition of adulterated drugs provided by the FDCA, rather than a state law definition in pursuing his claims, does not change that conclusion. Consequently, Defendants' assertion that the lack of a private right of action in

the FDCA operates to foreclose Mr. Lefaivre's claims in this case is, as *Wyeth* makes clear, flatly incorrect.

Finally, Defendants *admit* that both possible types of conflict are not present in this case. Memorandum at 10. Defendants state unequivocally that they "are not arguing that Plaintiff's claims are preempted by any state labeling law, nor that it is physically impossible to both comply with the FDCA and pay damages. Likewise, Defendants are not arguing that specific language in the FDCA explicitly prevents Plaintiffs from bringing state claims *relating* to the FDCA or FDA regulations…." *Id*. (emphasis in original). Defendants thus make clear that, under *Wyeth*, neither of the bases for conflict preemption exist in this case, such that this Court should determine that conflict preemption does not bar Mr. Lefaivre's causes of action.

2. Congress Clearly Did Not Intend to Preempt Claims for Damages Caused by the Sale of Prescription Drugs

Under the FDCA, the FDA actually cannot enforce the Act directly against pharmaceutical companies. Rather, it can make an assessment as to whether the Act or its regulations have been violated and either initiate a court action to enforce them or recommend the pursuit of criminal violations. Further, in court, it can only seek seizure of drugs, injunctive relief and civil penalties, not damages. Accordingly, at most, Congress intended the FDA to have exclusive jurisdiction over the decision as to whether to judicially seek drug seizures, injunctive relief or civil penalties or recommend criminal penalties, and the few cases holding that the FDCA preempts state law damages suits have erroneously gone too far.

Initially, review of the applicable enforcement provisions of the FDCA demonstrates that Congress intended to give the FDA exclusive jurisdiction over the right to initiate only a very limited set of actions in the court system. The FDCA grants the following rights to the FDA: (1) to recommend the initiation of an action for seizure of products to the Department of Justice (21

U.S.C. § 334); (2) to recommend pursuant of injunctions against companies and individuals alleged to have violated the FDCA (21 U.S.C. § 332(a)); (3) to recommend criminal charges (21 U.S.C. § 333(a)); and (4) in some situations, to assess civil monetary penalties (21 U.S.C. §§ 333(b) & (f), 335a, 360pp). It does not authorize the FDA to recommend to the Justice Department that it seek economic damages on behalf of consumers who, like Mr. Lefaivre and the members of the Class, purchased adulterated (and, thereafter, valueless) prescription drugs.[1]

If Congress had intended to foreclose consumers from pursuing claims for damages suffered as a result of purchasing adulterated drugs (adulterated as defined in the FDCA) by granting the FDA the sole right to pursue the enforcement provisions of the statute, it would either have given the FDA the right to pursue damages claims or it would have expressly provided that damages caused by FDCA violations are not recoverable. To hold otherwise would be to hold that Congress intended the injustice of consumers having no remedy whatsoever, either directly by their own lawsuits or indirectly through actions brought by the FDA, for injuries (economic or physical) caused to them by their consumption of adulterated drugs. As the discussion of the FDCA's legislative history in *Wyeth* demonstrates, Congress had no such intent.

In an unavailing attempt to argue to the contrary, Defendants rely on several cases in which courts have foreclosed Lanham Act claims by drug companies against their competitors in light of the courts' reluctance to interpret and apply the FDCA and its regulations without the FDA first having taken a position. Memorandum at 9 (*citing ETHEX Corp. v. First Horizon Pharma. Corp.*, 228 F. Supp. 2d 1048, 1055 (E.D. Mo. 2002); *Infa-Lab, Inc. v. KDS Nails Int'l,*

[1] The FDCA contains a provision authorizing the FDA in certain circumstances to seek repair, replacement, or refunds of medical devices. 21 U.S.C. § 360h(b). Obviously, this provision unique to medical devices is not at issue in connection with the claims in this case.

2009 WL 161197 (E.D. Cal. 2009); *Mylan Lab., Inc. v. Matkari*, 7 F.3d 1130 (4th Cir. 1993); *Braintree Lab, Inc. v. Nephro-Tech, Inc.*, 1997 WL 94237 (D. Kan. 1997)). Typical of these cases is the opinion in *First Horizon* in which a pharmaceutical company complained of a competitor's use of the term "generic" as implying FDA endorsement of the competitor's similar product even though the FDA made no such determination. 228 F. Supp. 2d at 1052-53, 1055. In dismissing the Lanham Act claim, the court expressed a reluctance to "usurp the FDA's authority to interpret and enforce its own regulations," ultimately deciding to dismiss the cause of action because "this Court would be forced to determine FDA policy in order to determine the truth or falsity of the 'generic' nomenclature." *Id.* at 1055.

The courts in the other cited Lanham Act cases dismissed the respective Lanham Act claims for essentially the same reason: to avoid usurping the role of the FDA to make an initial determination of FDCA violations where the Lanham Act claim was based upon an alleged FDCA violation and the FDA had not yet considered the issue. *Infa-Lab*, 2009 WL 161197, *4 (dismissing claims because "their adjudication 'would force the [c]ourt to rule directly on the legality of [defendant's] conduct before the FDA has had a chance to do so.'") (*quoting Summit Tech., Inc. v. Hi-Line Med. Instruments, Co.*, 933 F. Supp. 918, 943 (C.D. Cal. 1996) (citation and truncation in original));[2] *Mylan*, 7 F.3d at 1139; *Braintree*, 1997 WL 94237, *7.

Although these cases are far from clear in their reasoning (and sound more like primary jurisdiction cases than preemption cases), based upon the FDCA's limitation of enforcement/injunctive actions to the United States, they appear to infer a Congressional objective that only the FDA can make a decision to ask a court to find a violation of the FDCA,

[2] *Infa-Lab* involved state law claims in addition to a Lanham Act claim, but the court's reasoning in finding then preempted is essentially the same as in the cases involving only Lanham Act claims. *Compare Infa-Lab*, 2009 WL 161197, at *4, *with First Horizon*, 228 F. Supp. 2d at 1055.

regardless of the purpose for which the finding is requested. That reasoning is faulty. It does not logically follow that Congress intended to prevent persons injured by their purchases of adulterated drugs, whether physically or economically, from recovering damages for same just because it granted the FDA the exclusive power to decide whether to use the courts to enforce future compliance with the FDCA and to seek civil penalties for past violations. Certainly, that reasoning is at odds with the more recent *Wyeth* case, in which the Supreme Court held that Congress' failure to provide for a private right of action in FDCA for injuries created by prescription drugs did not show an intent on the part of Congress to bar such actions but rather evidenced Congress' intent and understanding that private actions could continue under state law.

3. Because the FDA Determined That the Tablets Are Adulterated Pursuant to the FDCA, This Court's Adjudication of Mr. Lefaivre's Causes of Action Usurps No FDA Authority.

Even if the cases relied upon by Defendants correctly held that the grant of exclusive jurisdiction to the FDA to enforce the FDCA bars private state law damages actions, their reasoning would not apply in this case. As set forth above, those cases reasoned that Congress gave the FDA the exclusive right to make an **initial** determination as to whether to file an action asking a court to make the ultimate determination as to whether the Act or its implementing regulations have been violated. And, in those cases, the FDA had made no such initial determination. It has made such a determination in this case.

Specifically, in this case, the FDA has already determined that the Tablets purchased by Mr. Lefaivre were adulterated, as defined in the FDCA, and Defendants have entered into a Consent Decree aimed at preventing their future sale of adulterated drugs. Exhibits 1 & 2 to Memorandum. Thus, in adjudicating Mr. Lefaivre's causes of action in this case, this Court will

not even potentially usurp any exclusive FDA authority to make an initial determination as to whether the Tablets were adulterated -- in direct contrast to the concerns articulated by the courts in the Lanham Act cases relied upon by Defendants. Simply put, because the FDA, with the acquiescence of Defendants, has already determined that the Tablets were adulterated, as defined in the FDCA, the Court's adjudication of Mr. Lefaivre's causes of action for damages presents no conflict with any supposed objective of Congress to give the FDA the exclusive right to make an initial determination of whether the FDCA was violated.

Accordingly, even if the Court was to accept their application of preemption to damages actions, the remaining cases relied upon by Defendants lend no support to their preemption argument in this case. In *Anthony v. Country Life Mfg., L.L.C.*, 2002 WL 31269621 (N.D. Ill. 2002), for example, the district court dismissed the plaintiff's cause of action under the Illinois Consumer Fraud Act, finding preemption because the plaintiff's cause of action was "premised solely upon a violation of the FDCA -- that defendant sold nutrition bars containing ingredients that the FDA had not approved and the FDA had not yet made a determination as to such a violation." 2002 WL 31269621, *3; *see also* Memorandum at 8 (*citing Anthony*). As in the Lanham Act cases, the Illinois district court's preemption analysis rested on the fact that the plaintiff's state law claim alleged FDCA violations even though the FDA had not previously determined that it believed that the defendant had, in fact, violated the Act. *Id*. To the extent the Court accepts its premise, *Anthony* is distinguishable for the same reasons as the Lanham Act cases, because in this case the FDA has already determined that the Tablets were adulterated.

Defendants' reliance on *Animal Legal Defense Fund Boston, Inc. v. Provimi Veal Corp.*, 626 F. Supp. 278 (D. Mass. 1986) (Memorandum at 8), is likewise misplaced, because the FDA had not in that case previously made a determination as to the defendant's failure to comply with the FDCA.

Further, in holding that preemption barred the Massachusetts consumer protection statute claim of the plaintiff, the court analyzed a different and more expansive statutory and regulatory scheme than the prescription drug provisions of the FDCA implicated in this case. *Animal Legal Defense Fund*, 626 F. Supp. at 282 ("the federal statutory and regulatory scheme involved here entails **two** federal statutes [the FDCA and the Federal Meat Inspection Act, 21 U.S.C. §§ 601, *et seq.*] and **two** federal agencies [the FDA and the United States Department of Agriculture]."") (emphasis added).

Riley v. Cordis Corp., 2009 WL 1606650 (D. Minn. 2009), and the case it relied upon, the Supreme Court's decision in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), also lend no support to Defendants' argument. In both cases, the courts found preemption in connection with medical devices, which are the subject of their own express preemption provision, 21 U.S.C. § 360k(a). *Buckman Co.*, 531 U.S. at 347-48; *Riley*, 2009 WL 1606650, *3-*5. Accordingly, neither is relevant to this case. However, they demonstrate, contrary to Defendants' claims, that any preemption finding must result from analysis under the three applicable preemption doctrines.

Furthermore, Justice Stevens' concurring opinion in *Buckman Co.* strongly supports that the FDA's prior action in this case conclusively negates any basis for a finding of conflict preemption. In describing a hypothetical scenario which parallels the actual posture of this case (in which the FDA has already acted), Justice Stevens wrote:

> This would be a different case if, prior to the instant litigation, the FDA had determined that petitioner had committed fraud during the [approval] process and had then taken the necessary steps to remove the harm-causing product from the market. Under those circumstances, Respondent's state-law fraud claim would not depend upon speculation as to the FDA's behavior in a counterfactual situation but would be grounded in the agency's explicit actions. In such a case, a plaintiff would be able to establish causation without second-guessing the FDA's decision making or overburdening its personnel, thereby alleviating the Government's central concerns regarding fraud-on-the-agency claims.

Buckman Co., 531 U.S. at 354 (Stevens, J., concurring). In this case, as in Justice Stevens' hypothetical in *Buckman Co.*, the FDA's prior action has, if necessary, cleared the way for Mr. Lefaivre to bring his claim for damages, given that there can be no conflict with the FDA's authority under the FDCA to make an **initial** determination as to whether the Act or its regulations have been violated.

Finally, Defendants' reliance on *In re Orthopedic Bone Screw Products Liability Litig.*, 193 F.3d 781 (3rd Cir. 1999) is also unavailing. Defendants cite the case for the irrelevant proposition that the FDCA itself creates no private right of action. Memorandum at 7, 11. In *Orthopedic Bone Screw Litig.*, the Third Circuit held that no legally cognizable claim for conspiracy to violate the FDCA exists because a conspiracy claim requires an underlying tort as a predicate. 193 F.3d at 788. That holding has no bearing whatsoever on the Court's consideration of whether the FDCA preempts Mr. Lefaivre's state law causes of action to recover damages, and, thus, lends no support to Defendants' argument.

In sum, conflict preemption clearly does not apply to bar Mr. Lefaivre's causes of action, and none of the cases Defendants rely upon changes this conclusion. The Court should accordingly reject the application of conflict preemption.

IV.

MR. LEFAIVRE PLEADS A VIABLE CAUSE OF ACTION FOR BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY

A. MISSOURI'S CHOICE OF LAW RULES MANDATE APPLICATION OF MISSOURI LAW TO MR. LEFAIVRE'S CAUSE OF ACTION FOR BREACH OF WARRANTY.

Defendants claim that under Missouri's choice of law rules, Rhode Island law (the law of Mr. Lefaivre's state of residence) should apply to his claim for breach of the implied warranty of merchantability. Memorandum at 11-13. Defendants, however, fail to properly apply

Missouri's choice of law rules and, thus, fail to address the significant contacts that mandate the application of Missouri law to Mr. Lefaivre's first cause of action.

Defendants note correctly that this Court must apply the choice of law rules of Missouri, and that Missouri courts apply the "most significant relationship" test in determining which state's law governs. However, in arguing that the test should result in the Court's application of Rhode Island law, Defendants rely on the conclusory "analysis" exemplified by cases such as *Rodriguez v. Mallinckrodt, Inc.*, 2007 WL 2811061 (E.D. Mo. 2007), and offer only the perfunctory assertion that because Mr. Lefaivre resides in Rhode Island and purchased Defendant's Tablets there, its law necessarily applies. Memorandum at 12-13. Pursuant to a straightforward examination of the "most significant relationship" test and application of its factors, Missouri law applies to Mr. Lefaivre's cause of action for breach of warranty.

A cause of action for breach of the implied warranty of merchantability sounds in tort.[3] *Witherspoon v. General Motors Corp.*, 535 F. Supp. 432, 434 (W.D. Mo. 1982); *Matulunas v. Baker*, 569 S.W.2d 791, 794 (Mo. Ct. App. S.D. 1978). With respect to the substantive law of torts, Missouri has adopted Section 145 of the RESTATEMENT (SECOND) OF CONFLICT OF LAW, which provides that the rights and liabilities of the parties are governed by the substantive law of the state with the "most significant relationship" to the occurrence and the parties. *See E. Me. Baptist Church v. Union Planters Bank, N.A.*, 244 F.R.D. 538, 547 (E.D. Mo. 2007).

[3] Defendants' citation to *Global Petromarine v. G.T. Sales & Mfg., Inc.*, 2008 WL 695395, *3 (W.D. Mo. 2008) for the proposition that "a breach of the implied warranty of merchantability is essentially a breach of contract claim, not a tort claim" (Memorandum at 12) is incorrect and improper. The district court in *Global Petromarine* made no such finding and preformed no such analysis. Rather it applied Section 188 of the RESTATEMENT (SECOND) OF CONFLICT OF LAW in the context of motion seeking summary judgment on a number of causes of action arising out of a written contract, including breach of contract, the primary cause of action. 2008 WL 695395, *2-*4.

"Pursuant to § 145(2) of the Restatement, the most significant relationship is determined by considering the following factors, *according to their relative importance*: (a) the place where the injury occurred; (b) the place where the conduct causing the injury occurred; (c) the domicile, residence, nationality, place of incorporation and place of business of the parties; and (d) the place where the relationship, if any, between the parties is centered." *Harter v. Ozark-Kenworth, Inc.*, 904 S.W.2d 317, 320 (Mo. Ct. App. 1995) (citation omitted) (emphasis added). "These contacts are to be evaluated according to their relative importance with respect to the particular issue." *Kennedy v. Dixon*, 439 S.W.2d 173, 181 (Mo. 1969).

In this case, Defendants consist of a Delaware corporation with its principal place of business in Missouri (KV Pharmaceutical Company), and two Missouri corporations with all of their locations, including their principal places of business, in Missouri (ETHEX Corporation and Ther-RX Corporation). Amended Complaint ¶¶ 2-4, 7. Mr. Lefaivre is a Rhode Island resident. Amended Complaint ¶ 1. All of the Tablets were manufactured in and distributed from Missouri. Amended Complaint ¶¶ 7 & 27. The FDA determined that the Tablets manufactured at and distributed from Defendants' Missouri facilities were adulterated. Amended Complaint ¶ 8. Mr. Lefaivre filled his prescription for the Tablets in Rhode Island. Amended Complaint ¶ 14. Mr. Lefaivre was damaged by the difference in value between the Tablets if they had conformed to FDA regulations (their full purchase price) and the value of the adulterated Tablets he actually received (zero dollars). Amended Complaint ¶ 25.

When this Court applies the factors of Restatement § 145 to the allegations of the Amended Complaint, the Court should find as follows: (a) the place where the injury occurred is Rhode Island, because Mr. Lefaivre purchased the Tablets there; (b) the place where the conduct causing the injury occurred is Missouri, because Missouri is where Defendants manufactured

and distributed the adulterated Tablets; (c) the domiciles, residences, nationalities, places of incorporation and places of business of the parties are Rhode Island (for Mr. Lefaivre) and Missouri (for Defendants); (d) the place where the relationship between the parties is centered is Missouri, if it is centered in any place, since Mr. Lefaivre and Defendants are not in direct privity with each other and the conduct that links them is Defendants' manufacture of the drugs in and their distribution of the drugs from Missouri.

The Court should determine that these factors favor the application of Missouri law, because Missouri law (consistent with the Restatement) makes clear that if the states in which the defendant's wrongful conduct occurred and the place where the plaintiff suffered injury differ and the place of injury bears little relation to the occurrence or the parties, "the place where defendant's conduct occurred will usually be given particular weight." *Union Planters Bank*, 244 F.R.D. at 547 (*citing* RESTATEMENT (SECOND) OF CONFLICT OF LAW § 145, cmt. e). Specifically, the Restatement states that:

> Situations do arise, however, where the place of injury will not play an important role in the selection of the state of the applicable law. This will be so, for example, when the place of injury can be said to be fortuitous or when for other reasons it bears little relation to the occurrence and the parties with respect to the particular issue (see § 146, cmt. *d-e*). ….
>
> When… the place of injury… is fortuitous and, with respect to the particular issue, bears little relation to the occurrence and the parties, the place where the defendant's conduct occurred will usually be given particular weight in determining the state of the applicable law.

RESTATEMENT (SECOND OF CONFLICT OF LAWS § 145, cmt. e) (emphasis in original).

In this case, from its plants in Missouri, Defendants manufactured and distributed drugs to wholesalers and pharmacies around the United States who, in turn, sold the drugs throughout the United States. The states where Mr. Lefaivre and the other members of the proposed Class actually consumed the drugs were completely fortuitous. Certainly, Rhode Island has no

connection whatsoever to the real issue in this case -- that Defendants knowingly manufactured adulterated drugs in Missouri and from Missouri shipped them to be sold and consumed around the country and around the world without any disclosure that they were adulterated. Under these circumstances, the Restatement strongly supports that the Court should find that the manufacture of the adulterated drugs in and distribution of the adulterated drugs from Missouri -- the place where the conduct causing the injury occurred -- constitutes the determinative factor and consequently requires the application of Missouri law.

Notably, in class actions complaining of a defendant's conduct emanating from the defendant's headquarters or facilities in a particular state that caused injury to customers throughout the country, courts applying the Restatement § 145 "most significant relationship" test have routinely applied the law of the state from which the defendant's conduct emanated to the named plaintiff and all the members of the proposed class. *See Grove v. Principle Mut. Life Ins. Co.*, 14 F. Supp. 2d 1101, 1106 (S.D. Iowa 1998) (applying Iowa law because, *inter alia*, "Iowa is the state from which the alleged nationwide fraudulent scheme was orchestrated."); *Cuesta v. Ford Motor Co.*, ____ P.3d _____, 2009 Ok. 24, 2009 WL 1066300 (Okla. April 21, 2009) (applying Michigan's breach of warranty law to a nationwide class of car owners); *Ysbrand v. Daimler Chrysler Corp.*, 81 P.3d 618, 626 (Okla. 2003) (applying Michigan law because "Michigan is where the decisions concerning the design, manufacture, and distribution of the minivans were made [and] Michigan is the only state where conduct relevant to all class members occurred."); *Bunting v. Progressive Corp.*, 348 Ill. App. 3d 575, 586 (Ill. App. 2004) (applying Illinois law to non-residents because the defendant's purported policy and practice at issue in the case was "designed and implemented by [defendant] at its principal office in Illinois"); *In re: Pennsylvania Baycol Third Party Payor Litig.*, 2005 WL

852135, *6 (Pa. C.P. 2005) (applying Pennsylvania law because, *inter alia*, "[Defendants] directed and controlled their national sales strategies with regard to TPP's from within Pennsylvania. Their refund policy was designed or coordinated within Pennsylvania."). *See also In re: Mercedes-Benz Tele Aid Contract Litig.*, 257 F.R.D. 46, 60 & 64-69 (D.N.J. 2009) (applying New Jersey's unjust enrichment law and the New Jersey Consumer Fraud Statute to a nationwide class pursuant to other Restatement sections which use very similar factors to evaluate the "most significant relationship").

B. MISSOURI LAW ALLOWS MR. LEFAIVRE TO SUE DEFENDANTS FOR BREACH OF WARRANTY WITHOUT THEM BEING IN PRIVITY.

A plaintiff in Missouri may bring a cause of action for breach of the implied warranty of merchantability against a defendant with whom he is not in privity. *Collegiate Enterprises, Inc. v. Otis Elevator Co.*, 650 F. Supp. 116, 118 (E.D. Mo. 1986); *Thorpe v. Hammons Sheet Metal Co.*, 991 S.W.2d 157, 158 fn. 1 (Mo. Ct. App. 1999).

C. MISSOURI LAW DID NOT REQUIRE MR. LEFAIVRE TO GIVE PRE-SUIT NOTICE TO DEFENDANTS OF THEIR BREACH OF WARRANTY.

In this diversity jurisdiction case, the Court's task is to rule on legal issues under Missouri law as it predicts the Missouri Supreme Court would rule. *Allstate Ins. Co. v. Blount*, 491 F.3d 903, 915 (8th Cir. 2007). This Court should find that the Missouri Supreme Court would hold that Mr. Lefaivre was not required to give Defendants pre-suit notice of their breach of warranty for two reasons: (1) because Missouri law does not require the buyer to give pre-suit notice of breach of warranty to a manufacturer with whom he is not in privity, and (2) Missouri law does not require a buyer to give pre-suit notice of a breach to a seller or a manufacturer if the seller or manufacturer already has actual notice of the breach.

1. Because Defendants Were Not "Sellers" as to Mr. Lefaivre, He Was Not Required to Give Them Notice.

The requirement that a buyer must give notice to a seller of the seller's breach of the implied warranty of merchantability is found in MO. REV. STAT. § 2-607(3). *Kansas City v. Keene Corp.*, 855 S.W.2d 360, 369 (Mo. 1993) (en banc). It provides that, "the buyer must within a reasonable time after he discovers or should have discovered any breach notify the *seller* of breach or be barred from any remedy…." MO. REV. STAT. § 2-607(3) (emphasis added). Thus, on its face, the Missouri statute only requires notice be given to a seller, not to a manufacturer who did not sell directly to the plaintiff.

Consistent with this, the Missouri Supreme Court has stated that, "…the buyer is only under a duty to notify the immediate seller, not the manufacturer." *Keene Corp.*, 855 S.W.2d at 369. Although that would seem to dispose of any argument that Mr. Lefaivre was required to give notice to Defendants, who were not his immediate sellers, Defendants may argue that *Keene Corp*. does not stand for the proposition that where only the manufacturer is sued, no notice must be given by the plaintiff to anyone, but rather only for the proposition that notice can be given to either the immediate seller or the manufacturer. In making this argument, Defendants may rely on the case cited in *Keene Corp*. in which the Missouri Court of Appeals held that "the plaintiff cannot escape the notice requirement even though it chose to sue only the manufacturer" and then held that notice to either the immediate seller or the manufacturer satisfies the notice requirement in a suit against the manufacturer even if there is no evidence that the immediate seller passed the notice on to the manufacturer. *Ragland Mills, Inc. v. General Motors Corp.*, 763 S.W.2d 357, 361 (Mo. Ct. App. 1989).

Based upon the facts in *Keene Corp.*, this Court should conclude that the Missouri Supreme Court did not accept this statement by the Court of Appeals, but rather meant exactly what it said when it said that the buyer is not under a duty to give notice to the manufacturer. In that case, there was no evidence that the plaintiff ever gave notice to either the manufacturer or the immediate seller. *Keene Corp.*, 855 S.W.2d at 369. Rather, the Missouri Supreme Court noted that the defendant manufacturer had learned of a problem from the immediate seller who learned of the problem from OSHA. *Id.* Since there was no evidence that the plaintiff gave notice to anyone, the Missouri Supreme Court necessarily held that a plaintiff need not give notice to anyone when he sues a defendant who was not his immediate seller.

Further, it makes no sense that the Missouri Supreme Court would accept the fiction indulged in by the Missouri Court of Appeals in *Ragland Mills* that a buyer giving notice to an immediate seller of a breach of warranty by the manufacturer somehow satisfies the policy underlying the notice requirement even if the immediate seller never brings it to the manufacturer's attention. Rather, this Court should find that the Missouri Supreme Court held in *Keene Corp.* (or would hold if asked) that Missouri law simply does not require pre-suit notice by the buyer to anyone if it sues a manufacturer that did not sell directly to it.

2. Additionally, Mr. Lefaivre Did Not Have to Give Pre-Suit Notice to Defendants Because They Already Had Actual Knowledge of Their Breach of Warranty.

At a minimum, even if it does not stand for the proposition that a plaintiff buyer need not give notice to anyone when he sues a defendant manufacturer who was not his immediate seller, *Keene Corp.* stands for the proposition that a plaintiff buyer need not give notice to a defendant manufacturer or seller which has actual notice of the circumstances underlying the breach of warranty. Specifically, in that case, the plaintiff produced no evidence that it ever gave any notice to either the immediate seller or the manufacturer. 763 S.W.2d at 361.

Rather, the evidence showed only that the defendant manufacturer had actual knowledge of the problem based upon information provided by the immediate seller. *Id.* Thus, *Keene Corp.* supports that the plaintiff need not give notice to anyone if the defendant has actual notice.

Notably, the leading commentators on the Uniform Commercial Code have observed that while there is a split of authority on the issue, the majority rule is that a plaintiff buyer need not give notice if the defendant seller or manufacturer has actual knowledge of the facts giving rise to the breach of warranty. J. White & R. Summers, UNIFORM COMMERCIAL CODE § 11-10 fn. 1 at 769-70 (West 5th ed. 1996). Further, this very Court predicted that Missouri would follow the majority rule, holding that "[i]t would be an unreasonable, if not absurd, construction of the statute to require a renewed notice of breach after acceptance of the goods under the facts herein involved [where the seller was necessarily fully aware of the breach prior to tender]." *Jay V. Zimmerman Co. v. General Mills, Inc.*, 327 F. Supp. 1198, 1204 (E.D. Mo. 1971).[4]

Crucially, Mr. Lefaivre has clearly pled that Defendants had actual pre-suit knowledge of their breach of the implied warranty of merchantability. Specifically, Mr. Lefaivre has pled that the FDA's inspections of Defendants' facilities established that all of the drugs manufactured by Defendants since at least May 18, 2007, have been adulterated, that the FDA's findings were communicated to Defendants and that Defendants recalled the Tablets as a result of their knowledge of the adulteration. Amended Complaint ¶¶ 8-13 & 30. This constitutes a more than sufficient pleading of actual notice on the part of Defendants, obviating the need for Mr. Lefaivre to have given any pre-suit notice to either Defendants or his immediate sellers.

[4] In a case arising under Ohio law, the Sixth Circuit disagreed with this holding. *Roth Steel Products v. Sharon Steel Corp.*, 705 F.2d 134, 152 (6th Cir. 1983). That ruling is not, however, binding upon this Court, both because it is was issued by the Sixth Circuit and because it involved Ohio law, not Missouri law. Further, it should not be persuasive to the Court, as it is at odds with Missouri law as set forth in *Keene Corp.*

3. If Necessary, Mr. Lefaivre Sufficiently Pled Pre-Suit Notice to Defendants In His Amended Complaint.

In the Amended Complaint in paragraph 14, Mr. Lefaivre pled that he discussed the problem of the adulterated Tablets with one of the pharmacies that sold the Tablets to him. At an absolute minimum, this constituted sufficient notice to Defendants under *Keene Corp.* and *Ragland Mills.* In *Ragland Mills*, the plaintiff merely brought his wrecked car to the automobile dealer from whom he had purchased it, and the automobile dealer inspected it. 763 S.W.2d at 361. Despite the fact that there was no evidence that the dealer ever communicated anything to the auto manufacturer, and despite the lack of evidence that the plaintiff communicated to the automobile dealer that he would be making any sort of claim, the Court of Appeals held that it was sufficient notice because notice of the existence of a problem given to an immediate seller constitutes sufficient notice to the manufacturer. *Id.*

As the Missouri Supreme Court held in *Keene Corp.*,

> The notice contemplated by the U.C.C. does not require any particular formality or detail as to the nature of the buyer's complaint. 'The content of the notification need merely be sufficient to let the seller know that the transaction is still troublesome and must be watched.' [Citation omitted]. In addition, the buyer is only under a duty to notify the immediate seller, not the manufacturer. [Citation omitted].

855 S.W.2d at 369.

Under these cases, Mr. Lefaivre's discussion of the problem with the adulterated Tablets with the pharmacy which sold the drugs to him more than satisfies any notice requirement that exists under Missouri law.

D. ALTERNATIVELY, RHODE ISLAND REQUIRES NEITHER PRIVITY NOR NOTICE UNDER THE CIRCUMSTANCES OF THIS CASE.

Defendants contend that if Rhode Island law governs Mr. Lefaivre's cause of action for breach of the implied warranty of merchantability, his failure to plead privity and notice requires dismissal of this cause of action. As to privity, Defendants rely upon outdated case law that has been superseded by statute. As to notice, Mr. Lefaivre satisfied that requirement by filing and serving the Original Class Action Complaint on Defendants. However, out of an abundance of caution, and regardless of whether Missouri or Rhode Island law applies to Mr. Lefaivre's claims, Mr. Lefaivre has now pled the pre-suit notice he gave to Defendants. Amended Complaint ¶ 14.

1. Rhode Island Law Does Not Require Privity in This Case.

Citing three Rhode Island Supreme Court cases[5] decided before the 1969 amendment of R.I. GEN. LAWS § 6A-2-318 (1956) and one recent Maryland federal district court case[6] that relied upon two of those old Rhode Island Supreme Court cases, Defendants argue that Rhode Island requires privity between a defendant manufacturer and a plaintiff in order for the plaintiff to recover based upon breach of the implied warranty of merchantability. Memorandum at 14. The rule requiring privity was long ago discarded by the Rhode Island Legislature, however:

> A seller's or a manufacturer's or a packer's warranty, whether expressed or implied, including but not limited to a warranty of merchantability provided for in § 6A-2-314, extends to any person who may reasonably be expected to use, consume, or be effected by the goods and who was injured by breach of the warranty.

R.I. GEN. LAWS § 6A-2-318 (1956) (as amended in 1969).

[5] *Henry v. John W. Eshelman & Sons*, 209 A.2d 46, 51 (R.I. 1965); *Wolf v. S.H. Wintman Co.*, 139 A.2d 84 (R.I. 1958); *Lombardy v. California Packing Sales Co.*, 112 A.2d 701, 704 (R.I. 1955).

[6] *Ace American Ins. Co. v. Grand Banks Yachts, Ltd.*, 587 F. Supp. 2d 697, 708 (D. Md. 2008) (applying Rhode Island law).

Of course, as the ultimate consumer of the adulterated drugs manufactured and distributed by Defendants, Mr. Lefaivre constitutes a person who could reasonably be expected to consume the drugs. Notably, since 1969, Rhode Island courts have routinely allowed drug consumers to bring breach of warranty claims against drug manufacturers with whom they were not in privity. *See, e.g., Oresman v. G.D. Searle & Co.*, 321 F. Supp. 449, 452-454 (D.R.I. 1971); *Castrignano v. E.R. Squibb & Sons, Inc.*, 546 A.2d 775, 783 (R.I. 1988).

2. Mr. Lefaivre's Filing and Service of His Original Class Action Complaint Constituted His Giving of Notice to Defendants.

While R.I. GEN. LAWS § 6A-2-607(3)(a) does require giving of notice to a seller in order to recover for breach of warranty, it does not specify the form that notice must take. The Rhode Island Supreme Court has held that the filing and service of a complaint by a plaintiff can constitute sufficient notice of a breach of implied warranty. *DiPetrillo v. Dow Chemical Co.*, 729 A.2d 677, 683 (R.I. 1999). Defendants claim incorrectly that *DiPetrillo* is limited to its facts. Memorandum at 13. In fact, in holding that a plaintiff's complaint satisfies the notice requirement, the Rhode Island Supreme Court cited the Alaska Supreme Court's opinion in *Shooshanian v. Wagner*, 672 P.2d 455, 462-63 (Alaska 1983) for the general proposition that the filing of a complaint by a consumer is sufficient notice. *DiPetrillo*, 729 A.2d at 683; *see also Shooshanian*, 672 P.2d at 462-63 ("The filing of a complaint is certainly not a bar to the negotiation and settlement of claims….Allowing a consumer's claim to serve as notice will not prevent a defendant manufacturer from raising the issue of timeliness if it has been prejudiced by an unreasonable delay."). As set forth above, out of an abundance of caution, and despite the Original Class Action Complaint itself constituting adequate notice, Mr. Lefaivre has filed his Amended Complaint pleading his giving of pre-suit notice. Amended Complaint ¶ 14.

V.

MR. LEFAIVRE HAS STATED A CLAIM AS TO THER-RX

Defendants ask the Court to dismiss Ther-Rx Corporation "because Ther-Rx is not an appropriate defendant to either claim." Memorandum at 14. To support this request, Defendants offer only a patently incorrect description of Mr. Lefaivre's allegations against Ther-Rx. *Compare* Memorandum at 14 ("Ther-Rx is not alleged to have participated in the manufacturer or the marketing of the Tablets") *with* Amended Complaint ¶ 7 ("Defendants manufacture, market, and distribute Metoprolol Succinate ER Tablets"). In light of Mr. Lefaivre's allegations that Ther-Rx, as one of the Defendants, manufactured and/or distributed the Tablets, Defendants' mere *ipse dixit* is not sufficient at the pleading stage to support the Court's dismissal of Ther-Rx Corporation. Mr. Lefaivre has, pursuant to Fed. R. Civ. P. 12(b)(6), pled sufficient facts to support claims against Ther-Rx. Amended Complaint ¶¶ 7-14, 23-30. The Court should deny Defendants' request accordingly.

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on August 26, 2009, the foregoing motion was filed electronically and served by mail on anyone unable to accept electronic filing. Notice of this filing will be sent by e-mail to all parties by operation of the Court's electronic filing system or by mail to anyone unable to accept electronic filing. Parties may access this filing through the Court's system.

/s/ Martin Woodward
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